[-X-10

EXHIBIT 10

IND LOG

IND/NDA	/DMF#: 31,86	il IIND	Doc T	SubType:	RESPONDENCE IND	10/11/96 Page 1
CI#:	· .	376	<u> </u>	Sub Date:	7/18/88	
Generic:	en e			Appr Date:		
		<u> </u>				
Product N	ame:	Estrostep				
Sarcode Se Re	r/ Date f# To: From:	RE/ Content	Report T s/Report No	itle/ Report No.		
B03104	0 Mon, Jul	18, 1988 Initial IN	D			
		Item Item Item Item	2: Investig 3: PR. 376 4: Chemis A) Dru B) Dru C) Env 5: Pharma	ctory Statement a ator's Brochure 5-364-001 try, Manufacturing g Substance/Drug g Label vironmental Assess cology and Toxico	sment Claim for Exclu	tion sion
B03104	Tue, Jul	26, 1988 FDA Let				
		Acknow	ledgement (of receipt of IND c	n 26-Jul-88; number	31, 861 assigned.
B03104	Mon, Aug	29, 1988 FDA Let	ter RE: App	proval		
		FDA ap	proval to pro	ceed and request	for additional informa	tion.
B03104	1 Fri, Sep	23, 1988 Protoco	Amendmen	t (New Investigat	or & Change in Protoc	ol)
		PR. 376 PR. 376	-364-002: -364-003: -364-005: nent #1: PR	. 376-364-001: 8	-Aug-88: Changes the	wording on Page 5 D.
B03104	2 Wed. Sep	28, 1988 Letter R	E: Response	to Request for In	formation	
		Respons 1) Patie 2) Patie	e to 28-Aug	g-88 request for in		
B03104	3 Wed, Sep	28, 1988 Protocol		t (New Investigat	ors)	
			-364-006: -364-007:			
B03104	4 Mon, Oct	10, 1988 Letter R	E: Response	to Request for In	formation	
		Further	definition of	breakthrough blee	eding and spotting.	
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CI#:			37	6] Sub	Date:	7/18/88	
Generi	c:			Аррі	Date:		
Product Name: Estrost			ep .				
			*				
Barcode	Ser/ Ref#	Date		RE/ Report Title/	Report No		
	NGI#	To:		Contents/Report No./			
en e		From:					
B03104	_ 5	Thu, Oct 2	0, 1988	Protocol Amendment (Ne	w Investig	ators & Change in Protoc	col)
			<u> </u>	PR. 376-364-004: PR. 376-364-008:			
				The New Investigator's S	ummary P	age for 376-364, Center	rs 6 and 7 was
	· · , , , , , , , , , , , , , , , , , ,			inadvertently left out. C	•	_	
	· · · · · · · · · · · · · · · · · · ·		-		42.		
B03104	6	Tue, Jan 1	7, 1989	Protocol Amendment (Ne	w Investia	ator)	·
				PR. 376-364-005:			
					······································		
B03104	7	Fri Mar 1	በ 1 080	Safety Report	·	<u> </u>	
		i ii, iviai i	0, 1303	Patient #: 79 (PLC)			
· · ·				PR. 376-364-004:			
				AE: Ruptured ovarian cys	t		
				Possibly drug related. AE #: None			
			<u></u>	AL ". NONC	<u> </u>		
					-		
B03104	8	Wed, Mar 2		Protocol Amendment (Nev	w Investiga	ator)	
				PR. 376-364-006:		- V. S. S.	
					-		
303104	9	Mon, Apr 1	0, 1989	Letter RE: Response to Re	quest for	Information	
		S. Sobel, MI	D	Response to FDA request			n R. Philip,
				MD (PR. 376	-364-006)	qualifications.	
			45 4 5				
B03104	10	Fri, Apr 2	1, 1989	Safety Report			
				Patient #: 33 (BDH)			
•				PR. 376-364-004 AE: Ovarian cyst, nausea,	vomiting	Overien nein	
•				Possibly drug related	vonating,	Ovarian pain	
				AE #: 001-0376-890004			
						· · · · · · · · · · · · · · · · · · ·	,
303104	11	Fri Anr 2	8, 1989	Protocol Amendment (Nev	v Investio	atorel	· · · · · · · · · · · · · · · · · · ·
	- 1	· · · · · · · · · · · · · · · · · · ·		PR. 376-364-002:	· mvesuye	10101	
				PR. 376-364-005:			
303104	12	Wed May 3	1 1080	Letter RE: Request for Info	rmation	<u>:</u>	
		S. Sobel		Request review and comm		R 376-369 (ultracound)	
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	/DMF#: 31,8	61 IND	Doc Type: FDA CO	RRESPONDENCE	10/11/96 Page 3
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CI#:		376	Sub Date:	7/18/88	3
Generic:			Appr Date:		7
Product N	ame•	Estrostep			7
				J. Argaka Magazara	
Barcode Se	r/ Date	RE/	Report Title/ Report No		
Re	f# To:	Contents/F	Report No./		
	From:				
B03104	13 Thu, Ju	1 06, 1989 Letter RE:	Request for Meeting		
	S. Sobel		meeting to discuss IND		d NDA 17-354 and 16-
		/23. FDA	A meeting shall be held 20	-Jul-89 at 10 am.	
B03104	14 Tue, Aug		Amendment (New Investig	ator)	
		PR. 376-3	169-000:		
B03104	15 Fri, Aug	04, 1989 Minutes o	f FDA Meeting		
		20-Jul-89	- FDA meeting to discuss	bioavailability.	
B03104		24, 1989 FDA Lette	r RE: PR. 376-369		
		PR. 376-3	69 is satisfactory.		
B03104	16 Wed, Sep	27, 1989 Minutes of	f FDA Meeting		
	1.00 A 1.00 4.00 A 1.00 4.00 A 1.00	···-	9: FDA meeting to discuss	bioavailability.	
B03104	·····	18. 1989 Letter RF	Agenda for pre-NDA mee	<u>1 20 Se de la companya de la compa</u> La companya de la companya de	
	S. Sobel		pre-NDA meeting agenda		
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B03104		27 1000 Appud Po			
	18 Fri, Oct	t 27, 1989 Annual Re Cutoff dat	te: 19-Oct-89		
B03104	T.o. No.		- DF - D		
003104	S. Sobel		r RE: Request for informatic		
	3. 3050		ility/bioequivalence meetir	•	
B03104	19 Wed Nov	29, 1989 Minutes of	f FDA Meeting		
	.5,7750,7407		: FDA meeting regarding	pre-NDA.	
303104	20 Fri, Dec	22 1080 Protocol A	mendment (New Investig	atori	
200104	ZU FII, Dec	PR. 376-3		ator)	
		1.1. 070-0			
700405	24 44				
303105	21 Mon, Jan	22, 1990 Protocol A PR. 376-3	mendment (New Investiga	ator)	
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Clif: 376			•	. • •	SubType:	IND	10/11/96 Page 4
Product Name Estrostep	CI#:			376	Sub Date:	7/18/88	
Seri	Gener	ic:			Appr Date:		
Sarcode Ser	Produ	ct Name:	* .	Estrosten			
Ref# To: Contents/Report No.f		ot 1101110.		Locatop]
22 Mon, Feb 05, 1990 Protocol Amendment (New Investigator) PR. 376-374-006:	Barcode		To:		그는 아내는 그는 그 그 그 그 없는 사람들은 그는 그는 그를 보고 있는 것 같아요. 그는 그를 보고 있는 것이다면 하는 것이다면 없는데		
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PR. 376-374-002:	303105	22	Mon, Feb (ator)	
PR. 376-374-002: PR. 376-374-002: PR. 376-374-004: PR. 376-374-004: PR. 376-374-008: PR. 376-374-008: PR. 376-374-008: PR. 376-374-008: PR. 376-374-007: PR. 376-374-							
303105 24 Mon, Feb 19, 1990 Protocol Amendment (New Investigator) PR. 376-374-004: PR. 376-374-008: PR. 376-374-008: PR. 376-374-008: PR. 376-374-007: PR. 376-374-0	303105	23	Mon, Feb 1	 · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	ator)	
PR. 376-374-004: PR. 376-374-008: 303105 25 Mon, Mar 12, 1990 Protocol Amendment (New Investigator) PR. 376-374-007: 303105 26 Thu, Mar 15, 1990 Letter RE: Request for Information S. Sobel Request approval for the following pertaining to NDA submission: 1) Draft tables 2) Case report tabulations 303105 27 Fri, Mar 30, 1990 Letter RE: Response to Request for Information S. Sobel 26-Mar-90 telephone coversation regarding Dr. R. Young's CV. 303105 28 Mon, Apr 23, 1990 Protocol Amendment (New Investigator) PR. 376-374-005: 303105 29 Mon, May 14, 1990 Letter RE: Response to request for information S. Sobel Response to FDA request for information. Randomization of patients for PR. 376-374. 303105 30 Wed, Jun 06, 1990 Protocol Amendment (Change in Protocol)				PH. 376-3	3/4-002:		
PR. 376-374-008: PR. 376-374-008:	303105	24	Mon, Feb 1	9, 1990 Protocol A	Amendment (New Investig	ator)	
PR. 376-374-007: PR. 376-374-007: PR. 376-374-007: PR. 376-374-007: PR. 376-374-007: PR. 376-374-007: PR. 376-374-007: PR. 376-374-005: PR. 376-374-				i			
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374. 303105 30 Wed, Jun 06, 1990 Protocol Amendment (Change in Protocol)	03105						
			S. Sobel		to FDA request for inform	ation. Randomization o	of patients for PR. 376-
Amondment #1, DD 276 274 002 and DD 276 274 0074 at 1 \ 4 14 00	03105	30	Wed, Jun 0	· · · · · · · · · · · · · · · · · · ·			
Amendment #1: PR. 376-374-002 and PR. 376-374-007 (only): 1-May-90: Increases the total enrollment by 14.							only): 1-May-90:
Fri, Jul 27, 1990 Letter RE: General Correspondence to FDA	303105			7, 1990 Letter RE:	General Correspondence	to FDA	
S.Sobel CI-376: Preparing NDA for Estrostep; request meeting with FDA to discuss formulation development and bioequivalence study requirements.			S.Sobel		•		

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IND/ND	JA/UIIII	F#: 31,861	IND	Doc Type: FDA CO SubType:	IND	10/11/96
CI#:			376	Sub Date:	7/18/88	<u> </u>
Generic	:			Appr Date:		
Product	: Name	•	Estrostep			
	Ser/ Ref#	Date To: From:	RE/ Contents/	Report Title/ Report No Report No./	o.	
B03108	40	Fri, Aug 1	6, 1991 Annual R	eport	·	<u>-14 - 15 , </u>
				e: 15-Aug-91 Period: 25-Jul-90 through	h 19-Jul-91	
B03108				: Preclinical Testing		
		Distribution		nt to P-D, in Dec-87, regar A copy of the letter was		-
		M. Taylor				
B03108	41	Thu, Apr 1	6, 1992 Information	on Amendment (Pharmaco	ology/Toxicology)	
			RR 724-0 developm	Research Report list for RR 00152: The market-image ental nature and will not b	tablets used in this study	y were of a
			anaiyses	were not performed.		
B03108	42	Wed, Sep 2	3, 1992 Annual R			
			Date: 23- Periods C	overed: 20-Jul-91 through	n 3-Jun-92	
B03109	43	Mon Nov O	8 1993 Information	on Amendment: Clinical		
		S. Sobel		e: 05/11/92		
				rch Report submitted. Research Report list for RR	t# , date, author and title) .
		M. Taylor				
B06494	44	Tue, Nov 0	9, 1993 Annual Re	eport	······································	
		S. Sobel		ce is made to our IND 31,8	861 for Estrostep® (nore	thindrone acetate and
			ethinyl estradio 1992	l) Tablets. Since the last /	Annual Report was subm	nitted on September 23,
•				la 042) usa hawa	information to report at	this time. We submitted
			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	io. 042), we have no new		
			a clinical s (Serial N	study report for Study 376 lo. 043). This study was s	summarized in the last a	November 8, 1993 nnual report. No clinical
			a clinical s (Serial N	study report for Study 376	summarized in the last a	November 8, 1993 nnual report. No clinical

IND/N	DA/DMI	F#: 31,86	1 IND	Doc Type:	FDA CORRI	SPONDENCE	10/11/96 Page 7
	· .	•	,	SubT	ype:	IND	
CI#:			376	Sub (Date:	7/18/88	
Generic	::			Appr	Date:		
Produc	t Name:		Estrostep				
	Ser/ Ref#	Date To: From:	RE/ Contents/	Report Title/ Report No./	Report No.		
B06494	45	Fri, Sep	09, 1994 Annual Re	eport	<u> </u>		
			ethinyl e Novemb time. N	estradiol) Tablets. er 9, 1993 (Seria	. Since the I al No. 044),	ast Annual Report w we have no new info	thindrone acetate and as submitted on ormation to report at this to keep this IND open for
		M. Taylor					
B06494	46	Fri, Aug	25, 1995 Annual Re	eport	<u>=</u>		
		S. Sobel	ethinyl es Septembe time. No	tradiol) Tablets. er 9, 1994 (Serial	Since the la: I No. 045), v	st Annual Report was ve have no new infor	nindrone acetate and s submitted on mation to report at this keep this IND open for
		M .Taylor					
B06494	47	Fri, Aug (30, 1996 Annual Re	port			
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		M. Taylor					